Michael Shipley (SBN 139582)
KIRKLAND & ELLIS LLP
555 South Flower Street, 37th Floor
Los Angeles, California 90071
Tel: (213) 680-8400
michael.shipley@kirkland.com

Devora W. Allon, P.C. (*Pro Hac Vice*)
Kevin M. Neylan, Jr. (*Pro Hac Vice*)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-4800
devora.allon@kirkland.com
kevin.neylan@kirkland.com

Attorneys for Plaintiff Teva Pharmaceuticals USA, Inc.

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff,

v.

CORCEPT THERAPEUTICS, INC., AND OPTIME CARE INC.,

Defendants.

Case No. 5:24-cv-03567-BLF

PLAINTIFF TEVA PHARMACEUTICALS USA, INC.'S OPPOSITION TO DEFENDANTS CORCEPT THERAPEUTICS, INC.'S, AND OPTIME CARE INC.'S, JOINT MOTION TO DISMISS

Date: February 20, 2025
Time: 9:00 a.m.
Ctrm: 3 - 5th Floor
Judge: Honorable Beth Labson Freeman

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INTRODUCTION

In a typical, competitive pharmaceutical market, a brand company enjoys high prices and a large market share until more affordable generic competitors enter the market—at which point prices quickly fall and patients rapidly switch from the brand drug to its generic equivalents. Federal and state laws work together to promote generic substitution, enabling generic drugs to drive down prices and capture large market shares so that patients can benefit from expanded access to more affordable medicines. That is what reliably happens when pharmaceutical markets work as intended. But not in the market for Korlym. Korlym is a brand drug that Corcept has sold since 2012. Korlym costs little to produce. But it has no substitutes, which has allowed Corcept to charge hundreds of thousands of dollars per patient, per year, at profit margins close to 99%. Korlym is Corcept's only product. To protect its monopoly and its only source of revenue from the existential threat of generic competition, Corcept has engaged in a years-long, multifaceted scheme to suppress generic competition.

Corcept's scheme has three parts. The first is an unprecedented exclusive dealing agreement between Corcept and its specialty pharmacy, Optime Care. Under this agreement, Optime has been the only pharmacy dispensing Korlym since 2017, which has entrenched Optime as the key distribution channel that alone can effectively reach Korlym patients. But Defendants' agreement hobbles competition by expressly forbidding Optime from distributing any rival products, including generic versions of Korlym. The second part of the scheme is Corcept's abuse of the patent system. By fraudulently listing patents in the FDA's Orange Book and filing sham patent infringement litigations, Corcept succeeded in delaying—by years—FDA approval and launch of generic Korlym. The third part of the scheme is a campaign by Corcept to pay bribes and kickbacks to induce prescribers to continue favoring brand Korlym over lower-priced generics.

The anticompetitive effects of this scheme are plain to see. Teva launched the first generic version of Korlym in January 2024. As a therapy, Teva's generic is identical to brand Korlym in all respects. And it has been priced at a material discount to Corcept's branded product since day one. But Teva has captured virtually zero market share—less than 1% of the market. A result like that is unheard-of. It would be impossible to explain in a properly functioning pharmaceutical market, where first generics reliably capture 60-75% of the market in their first six months, and around 80% in their

first year. As a result, Corcept and Optime's anticompetitive scheme has allowed Corcept to maintain its monopoly and to continue exploiting vulnerable patients by charging supracompetitive prices.

The details and effects of Defendants' anticompetitive scheme are painstakingly set forth in Teva's complaint. Teva's well-pled allegations easily establish a variety of anticompetitive tactics and significant, ongoing harm to Teva and to consumers. At every turn, Defendants misstate the law, ignore Teva's well-pled allegations, or both. Their motion should be denied.

BACKGROUND

Korlym is a once-daily pill that is indicated to treat certain patients with endogenous Cushing's syndrome, a rare and debilitating disease that occurs when the body produces too much cortisol. (¶¶58-64.)[1] The FDA approved Korlym in 2012. (¶68.) Korlym qualified as an "orphan drug" under federal law, a status that is "reserved for diseases and conditions that lack adequate treatments." (¶65-66.) As suggested by Korlym's orphan drug designation, Korlym has no substitutes. In fact, the FAC alleges—and Defendants do not dispute—that Korlym is in a market of its own, with the market properly defined to include only Korlym and its AB-rated generic equivalents. (¶¶188-201.) As a result, it is undisputed that during the nearly 12 years before Teva entered the market, Corcept had a 100% market share, and that Corcept's market share remains close to 100% even today. (¶¶191-92.)

Corcept has taken full advantage of its monopoly power. Publicly available data indicate that a single year's supply of Korlym costs anywhere from $244,000 to $980,000 *per patient*. (¶71.) For Corcept, those astronomical prices are almost all profit: Corcept's profit margins on Korlym are at least 98.7%, meaning Korlym's price is "77-times the marginal cost of manufacturing it." (¶72.)

Teva sought to break Corcept's monopoly in 2017 by filing an Abbreviated New Drug Application ("ANDA") to market a generic version of Korlym. (¶73.) The FAC describes the approval process for brand and generic drugs in detail. (¶¶21-56.) As relevant here, a generic drug can only be approved if the FDA determines it to be "bioequivalent" to the relevant brand drug, meaning it is identical in every pharmacological respect. (¶¶36-37.) As a result, "[t]he only material

[1] Unless otherwise noted, "¶" refers to Teva's First Amended Complaint ("FAC"), all internal citations and quotations are omitted, and all emphases are added.

difference between generic drugs and their corresponding brand-name versions is their price." (¶37.) Generic drugs are cheaper. On average, a first generic launches at a price discount of 18% compared to the brand. (¶49.) And to promote rapid switching from brand drugs to generics, "every state has adopted substitution laws that either require or permit pharmacies to substitute bioequivalent generic drugs for brand drug prescriptions." (¶50.) But these laws "can only operate as intended if the relevant pharmacy carries the generic version of the prescribed drug. Otherwise, the pharmacist has nothing to substitute, and must—of necessity—dispense the brand version." (¶53.) When the laws work as intended, pharmaceutical markets exhibit a predictable dynamic: "once a generic drug enters the market, it quickly captures sales of the corresponding brand drug, often capturing 60-75% or more of the market within the first six months, and usually more than 80% within the first year." (¶54.)

But that dynamic would have been disastrous for Corcept, because Korlym is not only a cash cow—it was (and remains) Corcept's only product, generating 100% of its revenue. (¶70.) Generic competition is thus an existential threat, which Corcept has tried to forestall by any means necessary.

Corcept's first tactic was to abuse the patent system and the courts to delay Teva's ability to obtain FDA approval and launch its generic Korlym. (¶¶73-122.) As the FAC explains, brand companies are allowed to list patents that cover their products in a publication called the FDA's Orange Book—but there are specific criteria that govern whether patents are eligible for Orange Book listing. (¶¶27-31, 90-96.) Orange Book listings are extremely consequential, because "[l]isting a patent in the Orange Book gives brand manufacturers the power, by later suing for infringement of that same listed patent, to trigger an automatic delay of FDA approval of competing generic products for 30 months—regardless of whether the patent is valid or infringed, and regardless of whether the patent was properly listed in the Orange Book." (¶30.) The FDA, however, "does not review brand companies' Orange Book listings to ensure that their patents are eligible to be listed there." (¶31.)

Corcept exploited that lack of oversight by listing two patents in the Orange Book for Korlym—the '348 and '495 patents—despite knowing that these patents plainly were not eligible to be listed there. (¶¶74-100.) As discussed further below, Defendants *do not dispute* that Corcept fraudulently listed the '348 and '495 patents in the Orange Book, for the sole purpose of enabling itself to trigger an automatic 30-month stay of FDA approval for Teva's generic. Nor could Defendants

dispute that charge; in fact, Corcept's CFO admitted on an earnings call "that the '348 and '495 patents do not have 'a direct read on the Korlym label' or any 'express connection' to the Korlym label," which was "a clear admission that Corcept knew the '348 and '495 patents never should have been listed in the Orange Book." (¶99.) As a result of Corcept's Orange Book fraud, Teva's FDA approval was delayed until August 2020. Had Corcept not fraudulently listed the '348 and '495 patents in the Orange Book, Teva would have received FDA approval as early as October 2018, and no later than February 2019, and in either case Teva would have launched shortly thereafter. (¶¶76-81.)

Corcept would eventually sue Teva for infringing the '348, '495, and seven other patents—nine patents in all—through four separate lawsuits filed between 2018 and 2023. As detailed in the FAC and discussed further below, Corcept filed all of these lawsuits as part of a bad-faith scheme to impede and delay Teva's market entry. (¶¶113-22.) Corcept ultimately voluntarily dismissed claims based on *seven* of those patents, and lost on the remaining two after a bench trial in late 2023. (¶120.)

Despite Corcept's Orange Book fraud and bad-faith patent litigation, Teva entered the market in January 2024. (¶123.) "Teva's generic launched at a 13% price discount compared to brand Korlym," which translated to savings of tens of thousands of dollars per patient, per year, and Teva has maintained a material price discount compared to brand Korlym ever since. (¶¶126-27.) Nevertheless, "Teva has not captured the expected 60-75% of the market that one nearly always sees. Instead, ***Teva's market share has been close to zero***, currently standing at approximately 1% of the Korlym market." (¶128.) The FAC reports that ever since Teva launched, Corcept's executives have repeatedly boasted on earnings calls that Teva has been unable to make inroads on Corcept's monopoly. (¶¶129-30.) To pick just one example, on July 29, 2024, Corcept's President of Endocrinology gloated that "'[t]he Teva product has been available in the channel for many months, so it's out there, but it has had very little impact on our business.'" (¶130.)

Teva's inability to penetrate the Korlym market is not for lack of effort. On the contrary—in addition to maintaining a material price discount compared to Corcept—"Teva's product is available and stocked at all major national wholesalers and a specialty wholesaler," Teva "has made and continues to make the product available to all major national specialty pharmacies, several regional

specialty pharmacies, and several other national retail pharmacies," and Teva has "secured pricing on government contracts." (¶158; *see also* ¶168 (describing additional efforts related to insurers).)

What Teva cannot do, however, is distribute its product through Optime. That is because of Defendants' unprecedented exclusive dealing agreement. The FAC describes the Corcept-Optime exclusive dealing agreement in detail. (¶¶135-66.) In short, since 2017, Corcept has distributed Korlym exclusively through Optime. (¶¶136-37.) But Defendants' agreement expressly forbids Optime from distributing competing products, including generic versions of Korlym. (¶136.) Defendants' agreement is "highly unusual in the pharmaceutical industry … an extreme outlier, and possibly unprecedented." (¶147.) And it has been extremely effective at stifling competition from Teva. As described at great length in the FAC, "Corcept spent years without competition (years beyond what Corcept lawfully should have enjoyed), and used that time alone on the market to spend millions of dollars cultivating relationships with physicians, incentivizing them to rely on the Optime distribution channel. Having developed entrenched physician prescribing behavior and a sticky distribution channel subject to high switching costs, Corcept is now in a position to thwart generic competition by blocking its rivals' access to that distribution channel—blocking the most efficient, effective, and profit-maximizing means of market entry—which is exactly what the exclusive-dealing agreement with Optime accomplishes, by prohibiting the dominant pharmacy from distributing generic competitors." (¶153; *see also* ¶¶148-66.) Teva's experience proves that "[t]he economic reality" in the Korlym market is that generics are "reliant on access to Optime to compete, but Corcept's exclusive agreement with Optime has cut Teva off from the key pharmacy pipeline that is necessary to permit Teva to compete effectively." (¶161.)

Were these anticompetitive effects not bad enough, they have been exacerbated by "a years-long campaign" by Corcept "to steer prescribers … away from Teva's generic—specifically, by bribing physicians and other practitioners to prescribe brand Korlym by making unlawful payments as compensation for prescriptions." (¶167.) The FAC alleges the details of this scheme at length. (¶¶167-87.) In brief, publicly available payment and Medicare prescription data shows that from at least 2017 through the present, Corcept has been making enormous payments to prescribers, right around the time those prescribers began submitting large numbers of Korlym claims to Medicare.

Nothing about these payments appears ordinary by industry standards. On the contrary, Corcept's payments "are astronomical and far outside the norm." (¶184.) Corcept has been making payments to prescribers that are multiples—sometimes double-digit, or even triple-digit multiples—of what similar prescribers received from *all other manufacturers combined* over the same time periods. (*Id.*)

The publicly available payment and prescription data described in the FAC is necessarily limited, and cannot reveal the full scope of Corcept's bribery and kickback scheme, including "details on which doctors have prescribed Korlym over the years, how much Corcept and any of its affiliates have paid them during that time, and whether the payments had any legitimate purpose." (¶173; *see* ¶¶171-72, 176, 180.) But the available data raises a strong inference that Corcept "has engaged in a years-long campaign to funnel illicit kickbacks to physicians as compensation for prescribing brand Korlym, and that this bribery campaign is ongoing." (¶173.) These allegations are supported by an extensive analysis of publicly available payment and prescription data, and are reinforced by the existence of an ongoing investigation into Corcept's prescriber payments by the U.S. Attorney's Office for the District of New Jersey, reporting by investigative journalists, and allegations by confidential informants in a securities class action. (¶¶167-87.) In light of this evidence, the FAC alleges that "Corcept's unlawful payments to physicians are a material factor that has caused physicians to continue prescribing brand Korlym, and routing their prescriptions to Optime, notwithstanding the availability of Teva's lower-priced generic," which has "contribut[ed] in material respects to Corcept's overall scheme to deny Teva access to the Korlym market." (¶186.)

ARGUMENT

When considering a motion to dismiss, the Court must "take all allegations of fact as true and construe them in the light most favorable to the nonmoving party." *Sinclair v. City of Seattle*, 61 F.4th 674, 678 (9th Cir. 2023). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)

Teva brings claims under Sections 1 and 2 of the Sherman Act, and various state-law analogs. "Section 1 of the Sherman Act prohibits unreasonable contracts or combinations in restraint of trade." *Feitelson v. Google Inc.*, 80 F. Supp. 3d 1019, 1026 (N.D. Cal. 2015); 15 U.S.C. §1. Section 2

violations consist of two elements: (1) possession of monopoly power—which here is undisputed as to Corcept—and (2) "maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 481 (1992); 15 U.S.C. §2. Defendants do not contend that there is any difference in the legal framework that applies to Teva's Section 1 and Section 2 claims.

I. TEVA'S EXCLUSIVE DEALING CLAIM IS PLAUSIBLE AND TIMELY.

A. Teva's Exclusive Dealing Claim Is Plausible On The Merits.

The law governing exclusive dealing is not complicated. An exclusive dealing contract violates the Sherman Act "if its effect is to foreclose competition in a substantial share of the line of commerce affected." *Tevra Brands LLC v. Bayer HealthCare LLC*, 2024 WL 1909156, at *3 (N.D. Cal. May 1, 2024). Courts consider several factors when assessing the anticompetitive effects of an exclusive dealing agreement, including whether the agreement has a "substantial foreclosure" effect, measured as "the percentage of the market foreclosed by [the] exclusive agreement[]," *id.* at *9-10; whether alternative distribution channels are effective at allowing the defendant's competitors to "reach the ultimate consumers of the product" in question, *id.* at *9; and whether the agreement is "short-term and easily terminable," *id.* at *7-8. Courts also consider whether an exclusive dealing agreement is "incentive-based," meaning whether it allows the defendant's rivals to "lure … away" the defendant's contracting parties by offering better terms. *Feitelson*, 80 F. Supp. 3d at 1030-31. In addition, courts have considered "whether the defendant engaged in coercive behavior" to pressure its counterparty to accept the exclusive arrangement, as well as whether "competitors of the defendant" employ similar exclusive dealing agreements. *In re Mylan N.V. Sec. Litig.*, 666 F. Supp. 3d 266, 292 (S.D.N.Y. 2023). Here, every one of these considerations favors Teva.

1. Defendants' agreement has a substantial foreclosure effect.

To determine the foreclosure effect of the Corcept-Optime exclusive dealing agreement, the Court must estimate "the percentage of the market foreclosed by [Defendants'] exclusive agreement[]." *Tevra*, 2024 WL 1909156, at *9. There are two steps to this analysis. The first step asks: in a properly defined market that includes Korlym, what percentage of product sales are subject to the exclusive agreement? The second step asks: are there alternative distribution channels that are

practically effective at allowing Teva to reach the ultimate consumers of Korlym—*i.e.*, patients and their health plans—bearing in mind that "[t]he mere existence of other avenues of distribution is insufficient without an assessment of their overall significance to the market." *Id.* If practically effective alternative channels exist, those alternative channels may be included in the denominator to calculate the percentage of the market that is foreclosed by Defendants' exclusive dealing agreement. *Id.* at *9-10. But if practically effective alternative channels do not exist, then the exclusive agreement's foreclosure effect is equal to the percentage of sales in the Korlym market that are distributed through Optime, *see id.*, which here is close to 100% (¶148).

This is the framework courts routinely use to calculate foreclosure effects in exclusive dealing cases. *See, e.g.*, *Tevra*, 2024 WL 1909156, at *9-10; *United States v. Microsoft*, 253 F.3d 34, 69-71 (D.C. Cir. 2001) (holding that an exclusive agreement's foreclosure effect is equal to "the share of the market foreclosed" by the exclusive agreement); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 286 (3d Cir. 2012) (basing foreclosure on the percentage "of the market remaining open," that is, not covered by the defendant's exclusive agreements); Areeda & Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶1821d4 (2024 online ed.) (explaining framework).

To answer the first question—in a properly defined market that includes Korlym, what percentage of sales are subject to Defendants' exclusive agreement—the Court must first define the relevant market. Here, that step is easy, because Defendants do not dispute that the relevant market is limited to brand Korlym and its AB-rated generic equivalents. (¶¶188-201.) The FAC's detailed allegations make clear that Korlym has no meaningful substitutes, which explains why Corcept has been able to charge hundreds of thousands of dollars per patient, per year, at profit margins of nearly 99%. (¶72.) The FAC's allegations further show that Corcept can unilaterally impose significant price increases without losing any noticeable business. (¶¶193-96.) Korlym's status as an orphan drug further indicates that Korlym and its generic equivalents are in a market of their own, because orphan drug status is reserved for drugs that treat conditions that *lack* alternatives. (¶66.) In light of these circumstances—and in particular, the demonstrated absence of any cross-price elasticity between Korlym and other products—it is no wonder that Defendants do not dispute Teva's allegation that the relevant market is defined as Korlym and its AB-rated generic equivalents. *See, e.g.*, *UFCW v. Teikoku*

Pharma USA, 296 F. Supp. 3d 1142, 1171 (N.D. Cal. 2017) (holding that "in the pharmaceutical context courts have limited the market to … the brand product itself in absence of cross-elasticity evidence"). And because *all* of Corcept's sales of brand Korlym go through Optime—and because Corcept's sales of brand Korlym account for nearly 99% of all sales in the Korlym market—it follows that the Corcept-Optime agreement has a foreclosure effect of approximately 99%. (¶148.)

The second question is whether that 99% foreclosure effect should be reduced to account for the presence of practically effective alternative distribution channels that Teva could use to "reach the ultimate consumers" of Korlym. *Tevra*, 2024 WL 1909156, at *9. The answer is no. The FAC's detailed allegations establish that alternative distribution channels might be theoretically available, but they are not practically effective as ways for Teva to reach the ultimate consumers of Korlym. Teva's allegations show that Teva has been working diligently to reach the ultimate consumers of Korlym by attempting to sell through other distribution channels. (¶¶158-60.) But Teva's allegations—and Corcept's own public statements—confirm that Teva *has not been able to reach end users of Korlym* through those alternative distribution channels. (¶¶158-60.) In Corcept's own words, "'we are not aware of losing any patients to generic mifepristone,'" and "'[t]he Teva product has been available in the channel for many months, so it's out there, but it has had very little impact on our business.'" (¶129-30.) That is why Teva's market share stands at around 1%, despite the fact that Teva has been the only generic version of Korlym on the market since January 2024, and has been priced at a material discount to brand Korlym for that entire time. (¶¶126-28.) Under the law of exclusive dealing, these facts mean that alternative distribution channels are not practically effective in the Korlym market, and should not be included in the "substantial foreclosure" analysis. *E.g.*, *Tevra*, 2024 WL 1909156, at *9-10; *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 196 (3d Cir. 2005).

As a result, the foreclosure effect of the Corcept-Optime exclusive dealing agreement is approximately 99%. Such a high foreclosure effect undoubtedly qualifies as "substantial foreclosure." *Tevra*, 2024 WL 1909156, at *10; *Feitelson*, 80 F. Supp. 3d at 1030.

Defendants have no good answer to this straightforward analysis. They first argue that Teva has failed "to define the relevant *distribution market* from which it alleges it has been foreclosed." (MTD Br. 17.) If Defendants are suggesting that the foreclosure analysis should focus on whether

Teva can contract with *other distributors*, that argument is plainly wrong. The question is not whether Teva can reach middlemen in the supply chain; the question is whether Teva can "reach the ultimate consumers" of Korlym, *i.e.*, patients. *Tevra*, 2024 WL 1909156, at *9. Furthermore, "[a]s the Ninth Circuit has made clear, 'the relevant market must be a *product* market,'" not a distribution market. *Nicolosi Distrib., Inc. v. FinishMaster, Inc.*, 2019 WL 1560460, at *6 (N.D. Cal. Apr. 10, 2019). As discussed above, the relevant market is indisputably defined as Korlym and its AB-rated generics. That is the market as to which foreclosure must be measured. *Tevra*, 2024 WL 1909156, at *9.

Defendants then insist that their exclusive agreement cannot have a substantial foreclosure effect because the relevant market cannot only include Optime, and because their agreement leaves Teva free to compete through distribution channels other than Optime, including other pharmacies and wholesalers. (MTD Br. 17-19.) This argument fails, because—as discussed above—under the law of exclusive dealing, alternative distribution channels are relevant only if they are *practically effective* at allowing the defendant's rival to "reach the ultimate consumers of the product" in question. *Tevra*, 2024 WL 1909156, at *9. Defendants' argument ignores this fundamental point.

For example, in *Tevra*, the Court explained that "[t]he mere existence of other avenues of distribution is insufficient without an assessment of their overall significance to the market." 2024 WL 1909156, at *9. The Court quoted the Third Circuit's influential opinion in *Dentsply*, in which the Third Circuit held that an exclusive distribution agreement in the market for artificial teeth was unlawful even though it only locked up certain dealers, and left rivals free to compete through other channels—including through other dealers and through direct sales, which could bypass dealers altogether—because "[t]he reality is that over a period of years, because of Dentsply's domination of dealers, [alternative distribution channels] have not been a practical alternative for most manufacturers. It has not been so much the competitors' less than enthusiastic efforts at competition that produced paltry results, as it is the blocking of access to the key dealers…. The reality in this case is that the firm that ties up the key dealers rules the market." 399 F.3d at 189-90.

The well-pled allegations in the FAC show that exactly the same dynamic is true in the market for Korlym. Corcept spent more than a decade alone on the market (including as a result of its unlawful Orange Book and patent litigation misconduct). It used that time without competition to establish

Optime as the key pharmacy that prescribers use to dispense Korlym, which competitors like Teva must be able to access if they want to threaten Corcept's monopoly. Teva's experience since launching is the most powerful evidence available that alternative pharmacies and wholesalers are not "a practical alternative," and that Corcept's ability to "tie[] up the key dealer" has allowed Corcept to "rule[] the market." *Id.* Contrary to Defendants' argument, "[t]he proper inquiry is not whether [alternative channels] enable a competitor to 'survive' but rather whether [competing through alternative channels] 'poses a real threat' to defendant's monopoly." *Id.* at 193. In this case, there is no question that alternative channels have not allowed Teva to pose a real threat to Corcept's monopoly.

Just a few months ago, Google made the same argument Defendants make here, in a major antitrust case brought by the Department of Justice, but the court had no trouble rejecting it and holding Google's exclusive agreements unlawful. *United States v. Google LLC*, 2024 WL 3647498, at *106 (D.D.C. Aug. 5, 2024). Like Defendants here, Google argued that "there is no foreclosure at all [in the market for general search engine queries] because [Google's] distribution agreements still permit rivals to compete for queries" through other channels. *Id.* The court rejected that argument because the evidence showed that Google's exclusive agreements locked up "the most efficient channel for reaching search consumers… Sure, users can access Google's rivals by switching the default search access point or by downloading a rival search app or browser. But the market reality is that users rarely do so. The fact that exclusive agreements allow users to reach rivals through other means does not make the foreclosure number zero." *Id.* The court's decision echoed this Court's analysis in *Feitelson*, 80 F. Supp. 3d at 1031—another case against Google—in which the Court recognized that "[a]s a practical matter, although other distribution channels for Internet search products do exist, the allegations demonstrate that the default search setting on mobile devices is the most effective and cost-efficient method of distribution. Taken as true, the allegations suggest that alternative distribution methods are viable but not effective compared to the default search setting status." The same is true here. As a practical matter, the market reality is that prescribers rarely send Korlym prescriptions to pharmacies other than Optime, which makes Optime the *only* efficient channel for reaching patients. That market reality means Defendants' agreement has a substantial foreclosure effect.

Many other cases reinforce the fundamental point that alternative distribution channels do not factor into the substantial foreclosure analysis *unless* market realities show that they are practically effective at allowing a rival to threaten the defendant's monopoly. For example, in *LePage's, Inc. v. 3M*, 324 F.3d 141, 160-62 (3d Cir. 2003), the Third Circuit held that 3M violated §2 by using exclusive dealing agreements to "cut LePage's off from key retail pipelines necessary to permit it to compete profitably," because—even though LePage's had alternative distribution channels open to it—3M's agreements "foreclosed LePage's from [the most] critical bridge to consumers." *Id.* at 160 & n.14. Likewise, in *Microsoft*, 253 F.3d at 70-71, the D.C. Circuit held that Microsoft's exclusive deals with Internet Access Providers violated §2 because—even though Microsoft's agreements did not foreclose all channels of competition—they "'severely restricted Netscape's access to those distribution channels leading most efficiently to the acquisition of browser usage share,'" and effectively helped "keep usage of Navigator below the critical level necessary for Navigator or any other rival to pose a real threat to Microsoft's monopoly." *See also, e.g.*, *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 240 (2d Cir. 2003) ("The most persuasive evidence of harm to competition is the total exclusion of American Express and Discover from a segment of the market for network services," even though Amex and Discover were free to attempt competing through alternative channels.).

Insofar as Defendants insist that their exclusive agreement does not foreclosure competition because Teva has the theoretical ability to compete through other channels, the response is simple: "market realities matter more than what is theoretically possible," *Google*, 2024 WL 3647498, at *100, and "[t]he paltry penetration in the market by [Teva] ... has been a refutation of [Defendants'] theory by tangible and measurable results in the real world," *ZF Meritor*, 696 F.3d at 285.

These cases also show that Defendants are wrong to assert that "Teva's attempt to state an antitrust claim based on others providing better services than Teva turns antitrust law on its head." (MTD Br. 19.) For one thing, Teva disputes that prescribers have continued choosing Optime only because Defendants provide better services than Teva. Rather, the FAC contains detailed allegations that (1) it is pretextual for Defendants to say they provide valuable services, given that Korlym is a once-daily oral pill that is easily administered and does not require the services of a specialty pharmacy (¶164); (2) prescribers continue relying on Optime because their prescribing patterns became

entrenched during the many years Corcept was the only competitor in the market, which Corcept used to cultivate relationships with the small number of prescribers in the market and to heavily promote both Korlym and Optime (¶¶149-54); (3) prescribers continue relying on Optime because the Korlym market is "sticky" and prescribers face high switching costs (¶¶159-66); and (4) at least some prescribers continue relying on Optime because Corcept is paying them illicit bribes and kickbacks (¶¶167-87). These detailed allegations must be assumed true at the pleadings stage, and they foreclose Defendants' assertion that Teva is merely attempting to free ride. In fact, Teva is *not* attempting to free ride; as alleged in the FAC, "Corcept could pay Optime to provide services to patients who receive brand Korlym, without forbidding Optime from distributing generic competitors—and patients who truly valued those services could simply pay a premium to stick with the brand and continue receiving whatever services Corcept and Optime provide. That Corcept has chosen *not* to compete on the merits in this fashion shows that the 'services' Corcept touts are pretextual, and that Defendants' unprecedented exclusive-dealing agreement serves no legitimate end." (¶165.)

In addition, even if prescribers *did* choose Optime solely because Defendants provide valuable services, that would not save Defendants' exclusive dealing agreement, because the caselaw makes clear *it is no defense* for a dominant firm to assert that a foreclosed distribution channel is simply more efficient than alternatives, or to insist that consumers have legitimate reasons to prefer the foreclosed distribution channel over alternative, but less effective, channels. For example, *Dentsply* catalogued a list of reasons why dental labs preferred purchasing false teeth through Dentsply's network of dealers, *see* 399 F.3d at 191-93, just as *Microsoft* explained why consumers preferred the Internet Explorer browser that was already installed on their desktops, *see* 253 F.3d at 70. *Feitelson* similarly recognized that Google's exclusive agreements cut rivals off from "the most effective and cost-efficient method of distribution," 80 F. Supp. 3d at 1031. In fact, in all of the cases discussed above, the distribution channel subject to exclusive dealing was the most efficient, cost-effective channel precisely because it was the channel consumers preferred. But those preferences only exacerbated the antitrust problem, because they explained why the exclusive agreements, which blocked competitors' access to those preferred distribution channels, were effective at foreclosing rivals and preserving the dominant firm's monopoly. Exactly the same is true here. (¶¶163-65.)

Defendants rely on the Ninth Circuit's *Omega* decision, but that case gives them no help because it is a post-trial decision and is fully consistent with the cases discussed above. In particular, *Omega* recognized that for purposes of a foreclosure effects analysis, alternative distribution channels are relevant only if they allow a competitor to "reach the ultimate consumers of the product" in reality, not just in theory. *Omega Env't, Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1163 (9th Cir. 1997). In *Omega*, "[t]he record contain[ed] undisputed evidence that direct sales to end-users [were] an alternative channel of distribution" that was highly effective at reaching consumers in reality, and the record contained additional "undisputed evidence of potential alternative sources of distribution" that would likewise be effective in practice. *Id.* Those market dynamics bear no resemblance to the market for Korlym, where Teva's experience and allegations show that alternative distribution channels are *not* effective at reaching the ultimate consumers of Korlym. Furthermore, in *Omega*, the exclusive contracts all had expiration dates within one year, and 90% of affected dealers were free to terminate their agreements for any reason "on 60 days notice," which meant that "a competing manufacturer need only offer a better product or a better deal to acquire their services." *Id.* at 1164. As discussed below, however, Optime is not free to terminate its exclusive arrangement with Corcept, no matter how good a deal Teva offers, which exacerbates the foreclosure effects of the exclusive agreement.

Defendants also misread *PNY Technologies., Inc. v. SanDisk Corp.*, 2014 WL 2987322 (N.D. Cal. July 2, 2014). In that case, the plaintiff failed to allege why it could not persuade the defendant's distributors to terminate their agreements and switch to the plaintiff, which indicated that the agreements were "short-term [and] easily terminable." *Id.* at *7-8. As discussed below, the situation with Corcept and Optime is the opposite. In addition, the plaintiff in *PNY Technologies* failed to allege that alternative distribution channels were practically ineffective at allowing it to "reach ultimate consumers." *Id.* at *9. Here, as discussed at length above, that is exactly what Teva has alleged.

2. Defendants' agreement is not short-term or easily terminable.

Defendants argue that their exclusive agreement does not raise antitrust concerns because it has a three-year term. (MTD Br. 19.) This argument fails for many reasons. As an initial matter, the exclusive arrangement has been in place since 2017—more than seven years ago—and it provides for automatic renewal on three-year terms. (¶137.) Moreover, even if three-year terms are not inherently

long-term, the FAC alleges in detail "that the contractual provisions at issue [are] '*de facto* long term and not easily terminable,'" because "the complaint 'sets out the reasons [Optime] allegedly cannot easily terminate [its] agreement[] with [Corcept]." *Tevra*, 2024 WL 1909156, at *1. For one, Optime does not "have a unilateral right to terminate without cause," and the agreement "can be terminated only upon breach," which means that Optime "cannot easily exit the agreement[]." *Google*, 2024 WL 3647498, at *108; (¶141). For another, the FAC alleges that Corcept uses "monetary levers to pressure [Optime] to exclusively carry [Corcept's] name brand [Korlym]." *Tevra*, 2024 WL 1909156, at *8. Specifically, as alleged in the FAC, "Optime was founded in 2015, and for many years, Corcept was its only supplier, and Korlym was the only drug it distributed. Those circumstances made Optime entirely dependent on Corcept; Optime could not risk losing its only supplier, and so felt obligated to accede to whatever terms Corcept demanded." (¶145.) To this day, "Optime remains heavily dependent on its relationship with Corcept for the survival of its business, and remains under intense pressure to accede to contractual terms demanded by Corcept. Statements from Optime employees to Teva made clear Optime's belief that if it were to distribute Teva's generic mifepristone product, Corcept would stop supplying it with brand Korlym and would likely never do business with it again. Such retaliation would be very damaging to Optime." (¶146.)

These circumstances mean the Corcept-Optime agreement "is not incentive-based," because Optime must remain in the agreement "regardless of whether adhering to the exclusivity provision is in Optime's best financial interests, and regardless of whether Teva or any other generic company offers lower pricing or other incentives that Corcept refuses to match." (¶144.) These dynamics were manifest on May 1, 2024, when Teva tried to lure Optime away from its exclusive arrangement by offering better terms. (¶139.) These efforts failed, because "Optime's representatives made clear that there was nothing Teva could do to gain access to the Optime distribution channel. Optime's employees described the agreement with Corcept as an 'evergreen' contract that effectively has no expiration date and that Optime is not free to terminate. During this meeting, Optime representatives would not even entertain a bid from Teva, even though Optime could potentially make more money by distributing Teva's generic…. Optime explained that it was not allowed to distribute Teva's product, no matter what terms Teva might propose." (¶139.)

Under the law of exclusive dealing, these facts easily demonstrate that Defendants' agreement is not short-term or easily terminable. *Tevra*, 2024 WL 1909156, at *8 ("This evidence of pressure and monetary incentives not to carry imidacloprid generics is enough to create a genuine dispute of material fact as to whether Bayer's agreements are not short-term and easily terminable."); *Feitelson*, 80 F. Supp. 3d at 1030-31 (exclusive agreement raises antitrust concerns if it is not "incentive-based"). Simply put, "[t]his is not a market where 'a competitor can simply wait for contracts to expire or make alluring offers to initiate termination,'" and this "lack of flexibility for [Optime] to exit the distribution agreement[] reinforces [its] foreclosure effect." *Google*, 2024 WL 3647498, at *108-09.

3. Other considerations demonstrate the agreement's anticompetitive effects.

In addition to the factors discussed above, courts evaluating exclusive dealing agreements consider "whether the defendant engaged in coercive behavior" in convincing its distributor to accept the exclusive arrangement, as well as whether "competitors of the defendant" use similar exclusive dealing agreements. *In re Mylan*, 666 F. Supp. 3d at 292; *ZF Meritor*, 696 F.3d at 271-72, 284-85.

As to the coercive nature of the agreement, the allegations recounted above show that Optime's heavy degree of financial dependency on Corcept has allowed Corcept "to coerce … one-sided terms in its agreement with Optime." (¶145.) Specifically, "the agreement is severely one-sided in favor of Corcept," including because "Corcept has the right to terminate the distribution agreement for convenience at any time, but Optime does not," and that Corcept has the right to render the agreement non-exclusive with respect to itself—meaning Corcept can unilaterally give itself the right to distribute Korlym through other pharmacies—but "Optime has no similar right to modify its obligation to exclude all products that compete with Korlym." (¶¶140-41 & n.111.) This evidence of coercion heightens the antitrust concerns. *ZF Meritor*, 696 F.3d at 272; *Mylan*, 666 F. Supp. 3d at 292.

In addition, there is no comparable "use of exclusive dealing" by Defendants' competitors. *ZF Meritor*, 696 F.3d at 272; *Mylan*, 666 F. Supp. 3d at 292. This "agreement is highly unusual in the pharmaceutical industry. Teva does not have—and is not aware of other manufacturers having—any such agreements with pharmacies that include this sort of one-sided, blanket, perpetual exclusivity that expressly forbids the pharmacy from distributing competitor products." (¶147.)

On top of all that, the Corcept-Optime agreement is highly detrimental to competition because it circumvents state generic substitution laws. As explained in the FAC, state substitution laws are designed to promote rapid switching from brand drugs to generic drugs upon generic entry, to save consumers money, but substitution laws cannot function if a prescription is routed to a pharmacy that does not stock the generic. (¶¶50-53.) The Corcept-Optime agreement is therefore especially anticompetitive because it frustrates "the operation of state substitution laws," and "'deprives potential generic manufacturers a prescription base for their generic version of the [brand] drug,'" because when Korlym prescriptions are routed to Optime, "the brand drug cannot be automatically substituted for the generic at the pharmacy counter." *Iron Workers Dist. Council of New England Health & Welfare Fund v. Teva Pharm. Indus. Ltd.*, 2024 WL 2025572, at *2 (D. Mass. May 7, 2024). This anticompetitive effect is by design. In fact, Corcept has publicly boasted about having "put in place a 'tightly controlled model' that ensures that 'this is not your typical pharmaceutical market' and 'automatic substitution does not happen ... like you see in a lot of these cases.'" (¶156.)

B. Teva's Exclusive Dealing Claim Is Timely.

Defendants argue that Teva's exclusive dealing claim is time-barred under the Clayton Act's four-year statute of limitations, because Corcept and Optime first entered an exclusive arrangement in 2017. This argument is wrong many times over. As an initial matter, "statute of limitations defenses often require a fact-intensive investigation that is inappropriate on a motion to dismiss." *24/7 Customer, Inc. v. 24-7 Intouch*, 2015 WL 1522236 at *4 (N.D. Cal. Mar. 31, 2015). Regardless, Defendants' statute of limitations argument fails for numerous independent reasons.

First, Defendants overlook that Teva's generic Korlym did not enter the market until January 2024, and was *legally forbidden* from entering the market until it obtained FDA approval in August 2020. (¶¶45, 77, 123.) As a result, Teva had no cause of action to challenge Defendants' exclusive dealing agreement until January 2024, and could not possibly have had a cause of action before August 2020, because "a cause of action" only "accrues" under the antitrust laws when a plaintiff "feels the adverse impact of an antitrust conspiracy." *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 401 U.S. 321, 339 (1971). Defendants' exclusive dealing agreement has injured Teva by "blocking Teva's access to the key distribution channel and cutting off patients from accessing Teva's lower-priced generic

product." (¶5.) But that "injury" was not inflicted until Teva entered the market and felt the effects of the exclusive dealing agreement, and *could not have been inflicted* during a time when Teva was legally forbidden from being on the market. As the Supreme Court recently explained, "a cause of action accrues 'on the date that damage is sustained and not the date when causes are set in motion which ultimately produce injury.'" *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 144 S. Ct. 2440, 2451 (2024). Teva's cause of action thus did not accrue until January 2024, and could not possibly have accrued before August 2020. Either way, this suit—filed in June 2024—is timely.

Second, Teva could not have challenged Defendants' exclusive dealing agreement before its product was on the market—and certainly not before it had FDA approval—because Teva would not have been able to allege causation or antitrust injury, which again proves that Teva's cause of action accrued within the limitations period. As the Supreme Court has explained, "a cause of action 'does not become complete and present for limitations purposes'—it does not *accrue*—'until the plaintiff can file suit and obtain relief." *Id.* But Teva would not have been able to file suit and obtain relief until its product had FDA approval and was on the market. *E.g.*, *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 2009 WL 10674453, at *2-3 (C.D. Cal. May 15, 2009) ("To state any substantive antitrust claim, Amphastar must allege that Aventis caused it antitrust injury. To suffer antitrust injury, Amphastar must be 'an actual competitor or one ready to be a competitor.'… However, Amphastar is presently excluded from the market because it lacks FDA approval…. Therefore, … Amphastar does not plead causation and antitrust injury."); *Bourns, Inc. v. Raychem Corp.*, 331 F.3d 704, 711 (9th Cir. 2003) ("Only an actual competitor or one ready to be a competitor can suffer antitrust injury."); *Ethypharm S.A. France v. Abbott Lab'ys*, 707 F.3d 223, 237 (3d Cir. 2013) ("Ethypharm did not suffer antitrust injury because it does not and indeed cannot compete in the United States fenofibrate market, unless and until it acquires the required FDA approval to do so.").

Third, it is well established that the antitrust statute of limitations does not begin to run if a lawsuit would be too speculative to support a cause of action—and it is equally well established that a lawsuit by Teva would have been too speculative before Teva obtained FDA approval and entered the market. *E.g.*, *Samsung Elecs. Co. v. Panasonic Corp.*, 747 F.3d 1199, 1204-05 (9th Cir. 2014) ("At the time of the adoption of the 2003 license, Samsung was not in the SD card market, and neither

Samsung nor the SD Defendants could have known for certain whether Samsung would enter that market…. Because the harm to Samsung challenged in this suit was speculative at the time of the initial wrong, the law of limitations in federal antitrust actions allowed Samsung to file suit once the harm crystallized in 2006 [*i.e.*, when Samsung entered the market]."); *Oliver v. SD-3C LLC*, 751 F.3d 1081, 1087 (9th Cir. 2014) (holding that antitrust statute of limitations did not run until plaintiff entered the market because antitrust suit before then would have been too speculative).

On top of all that, Defendants have taken multiple actions that restarted the limitations period on their exclusive dealing agreement. First, the FAC alleges that Defendants have amended their agreement "three times since 2017," changing the terms each time, including twice in 2022 and a comprehensive amendment in 2024. (¶¶138, 143 & n.111.) Each amendment restarted the limitations period. *Samsung*, 747 F.3d at 1204 (statute of limitations restarts "when conspirators continue to meet to fine-tune their cartel agreement"). Second, Defendants took actions to enforce their exclusive agreement in May 2024, when Optime refused to "entertain a bid from Teva" because "the exclusivity provisions" of Defendants' agreement forbade Optime from distributing Teva's product, "no matter what terms Teva might propose." (¶139.) That was an "overt act" that restarted the limitations period. *Samsung*, 747 F.3d at 1203-04 ("[A]n action taken under a pre-limitations contract [is] sufficient to restart the statute of limitations so long as the defendant had the ability not to take the challenged action, even if that would have required breaching the allegedly anti-competitive contract…. We have repeatedly held that acts taken to enforce a contract were overt acts that restarted the statute of limitations."). Third, the limitations period restarted every time Defendants took actions to "steer" patients to Optime, *id.* at 1203, which they have done—and continue to do—through a variety of ongoing tactics alleged in the FAC. (*E.g.*, ¶¶150-56, 161-66, 167-87.)

Defendants have no good response to these arguments. Defendants fail to acknowledge that Teva only received FDA approval in August 2020, and only entered the market in January 2024—which means the clock could not have begun running until August 2020 (at the earliest) for the variety of independent reasons set forth above. That oversight alone is sufficient to defeat Defendants' statute of limitations argument. In addition, Defendants insist that their three contractual amendments did not restart the limitations period because the amendments supposedly did not change the exclusivity

provision (MTD Br. 16), but this argument misstates the law; the statute of limitations restarts "when conspirators continue to meet to fine-tune their cartel agreement," full stop, *Samsung*, 747 F.3d at 1204, which Defendants unquestionably have done at least three times since 2022. Plus, unredacted versions of the agreement are not publicly available, so it is impossible to say whether the amendments affected the exclusivity provision. Defendants also assert that the Teva-Optime meeting in May 2024 was insufficient to restart the clock because the FAC des not allege who attended the meeting (MTD Br. 16-17), but again, that is not the law; Defendants cite nothing in support of that argument, and the FAC clearly pleads that Optime took actions under the agreement when it refused to entertain a bid from Teva, which is all the law requires to restart the clock. *Samsung*, 747 F.3d at 1203-04.

II. TEVA'S ORANGE BOOK CLAIM IS PLAUSIBLE AND TIMELY.

Defendants do not dispute that the '348 and '495 patents were improperly listed in the Orange Book, and they do not dispute that Corcept *knew* those patents were ineligible, but listed them anyway in order to delay Teva's FDA approval and launch. (¶¶83-100.) Nor could they. In fact, in 2019, Corcept's CFO publicly "admitted that the '348 and '495 patents do not have 'a direct read on the Korlym label' or any 'express connection' to the Korlym label," which was "a clear admission that Corcept knew the '348 and '495 patents never should have been listed in the Orange Book, because … FDA regulations have long provided that a brand company is only permitted to list a method-of-use patent in the Orange Book if it can 'identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent.'" (¶99.)

Defendants also do not dispute the anticompetitive consequences: by improperly listing the '348 and '495 patents in the Orange Book, Corcept unlawfully gave itself the power to trigger an automatic 30-month stay of FDA approval for Teva's generic. (¶76.) After triggering the 30-month stay, Teva's generic was barred from receiving FDA approval until August 2020—whereas, if the 30-month stay had not been triggered, Teva would have received FDA approval and launched as early as October 2018, which is when Teva received tentative approval in the real world. (¶79.) Abusing the Orange Book in this way is a recognized species of anticompetitive conduct that qualifies as an "'improper means' of maintaining [monopoly] power." *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 7 (1st Cir. 2020); *UFCW v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 124 (2d Cir. 2021).

A. Teva's Orange Book Claim Alleges Antitrust Injury.

Defendants argue that Teva fails to allege that Corcept's Orange Book fraud caused Teva to suffer any injury. This argument is preposterous. The FAC clearly explains that Corcept's unlawful Orange Book listings allowed Corcept to trigger an automatic 30-month stay of FDA approval, with the result that Teva could not receive FDA approval until August 2020 at the earliest. (¶76.) Absent the stay, the FAC alleges that Teva would have received final FDA approval and launched as early as October 2018, which is when Teva received tentative approval in the real world. (¶79.)

Defendants' response is that Korlym was granted orphan drug exclusivity in 2012, and Korlym was eligible to retain that exclusivity until February 2019—which means that even if Corcept had not illicitly triggered the 30-month stay, Teva would have been unable to obtain final FDA approval until Korlym's orphan drug exclusivity expired in February 2019. This argument fails for two reasons.

First, the FAC includes plausible allegations that Corcept forfeited its orphan drug exclusivity at some point before October 2018. (¶¶77-79.) In the FDA's October 2018 tentative approval letter to Teva, the FDA listed all of the regulatory obstacles that prevented Teva from receiving final approval at that time—but Korlym's orphan drug status was not on the list, even though federal regulations require the FDA to "notify [a generic drug company] in writing" if final "approval is barred under [the Orphan Drug Act]." (¶78 (quoting 21 C.F.R. § 316.31(c)).) The FDA's silence with respect to Korlym's orphan drug exclusivity raises a plausible inference that Korlym forfeited its exclusivity at some point before October 2018, which is entirely possible under federal regulations. (¶78 & n.51.)

Second, even if Korlym had retained its orphan drug exclusivity, that exclusivity would have expired in February 2019, and Teva would have received final FDA approval at that time if Corcept had not illicitly triggered the 30-month stay. "In that scenario, Teva still would have received final FDA approval almost 18 months earlier than it did in the real world, as a result of the 30-month stay triggered by Corcept's fraudulent listing of the '348 and '495 patents in the Orange Book." (¶80.) Hence, regardless of whether Korlym had orphan drug exclusivity through February 2019, Corcept's Orange Book fraud caused Teva to suffer serious antitrust injury by delaying its approval and launch.

Defendants also argue that Teva's Orange Book claim does not allege antitrust injury because *other factors* may have contributed to the delayed entry of Teva's generic, including Teva's decision

not to enter the market by launching "at risk" in August 2020. (MTD Br. 9.) This argument fails for several reasons. First, the law is clear that an antitrust plaintiff "need not rule out 'all possible alternative sources of injury,'" and that an "antitrust violation need not be the 'sole' cause of the injury for causation to exist." *Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1509 (9th Cir. 1985). Indeed, "if the plaintiff states sufficient facts to support his allegations that an antitrust violation has occurred and that he has sustained injury to his business or property, he is generally entitled to go to the jury on the violation and injury issues." *Solinger v. A&M Recs., Inc.*, 586 F.2d 1304, 1309 (9th Cir. 1978). On a motion to dismiss, Defendants cannot prevail by insisting that their antitrust violations may not have been the *only* reason for Teva's delayed launch. Tellingly, Defendants do not cite a single case holding that a competitor's decision not to launch at risk precluded the competitor from establishing causation with respect to a claim of fraudulent Orange Book listings or sham patent litigation. That is unsurprising, because "[w]hether a generic manufacturer is willing to risk treble damages from a patent infringement suit by selling a generic drug at risk is a generally a factual issue." *UFCW v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1074 (N.D. Cal. 2014).

Moreover, it is a red herring for Defendants to focus on Teva's decision not to launch at risk in the real world, because in the but-for world, Corcept would not have fraudulently listed the '348 and '495 patents in the Orange Book in the first place, and would not have brought sham patent litigations against Teva at all. Hence, in the but-for world, Teva would have received FDA approval either in October 2018 or February 2019, and no patent infringement claims would have been pending against it. Defendants have no basis to dispute that Teva would have launched immediately under those circumstances—which is what the world would have looked like if Corcept had not violated the antitrust laws. (¶¶79-80.) Teva's allegations are thus more than sufficient to plead that Corcept's Orange Book fraud caused Teva antitrust injury by delaying Teva's approval and launch.

B. Teva's Orange Book Claim Is Timely.

Defendants' statute-of-limitations argument fails for many of the same reasons it fails with respect to Teva's exclusive dealing claim. *First*, under the Ninth Circuit's decisions in *Samsung*, 747 F.3d at 1204-05, and *Oliver*, 751 F.3d at 1087, the clock did not start until Teva received FDA approval and entered the market, because any suit before then would have been too speculative to support a

cause of action. *Second*, Teva could not have filed suit on its Orange Book claim before it obtained FDA approval and entered the market, because it would have been unable to show antitrust injury and causation. As the court held in *Aventis*, 2009 WL 10674453, at *2, "*any* substantive antitrust claim" by a competitor in the pharmaceutical industry would fail if the competitor "lacks FDA approval." *See also, e.g.*, *Ethypharm*, 707 F.3d at 230, 237 (holding that a competitor's "antitrust and sham litigation claims" fail for lack of antitrust standing "unless and until it acquires … FDA approval"). *Third*, the statute of limitations on Teva's Orange Book claim restarted every time Defendants took "new and independent act[s]" that "inflict[ed] new and accumulating injury" on Teva. *Samsung*, 747 F.3d at 1202-04. Such new and independent acts include Defendants' amendments to their exclusive dealing agreement in 2022 and 2024 (¶138), their numerous and ongoing acts to "steer" patients to Optime (¶¶150-56, 161-66, 167-87), and the sham lawsuits that Corcept brought against Teva between 2018 and 2023 (¶¶113-22). All of these acts were "new and independent" of Corcept's improper Orange Book listings, and they all "inflict[ed] new and accumulating injury" on Teva by exacerbating the harms from Corcept's Orange Book misconduct, as parts of the same overarching anticompetitive scheme. *Samsung*, 747 F.3d at 1202-04. Nothing more is required to restart the clock.

III. TEVA'S PATENT LITIGATION CLAIMS ARE PLAUSIBLE AND TIMELY.

From 2018 to 2023, Corcept asserted nine patents against Teva in four lawsuits. Corcept voluntarily dismissed all claims based on seven of those patents, and lost resoundingly after trial on the other two. (¶¶120-21.) These claims were all shams and are actionable under the antitrust laws.

A. Corcept's Infringement Suits Were Shams Under *Noerr-Pennington*.

Defendants cannot secure dismissal by invoking *Noerr-Pennington* immunity. As an initial matter, "courts rarely award *Noerr-Pennington* immunity at the motion to dismiss stage, where the Court must accept as true the non-moving party's well-pleaded allegations." *Sonus Networks, Inc. v. Inventergy, Inc.*, 2015 WL 4539814, at *2 (N.D. Cal. Jul. 27, 2015). "[W]hether something is … a mere sham for *Noerr-Pennington* purposes, is a question of fact." *In re Xyrem (Sodium Oxybate) Antitrust Litigation*, 555 F.Supp.3d 829, 877 (N.D. Cal. 2021).

In any event, the FAC clearly pleads the "sham litigation" exception to *Noerr-Pennington*. "The sham litigation exception to *Noerr-Pennington* immunity requires an antitrust plaintiff to

demonstrate two things: first, that the prior lawsuit upon which the antitrust case is based was 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits' and second, that the subjective motivation behind the prior lawsuit was to directly interfere with a competitor's business relationships." *IPtronics Inc. v. Avago Techs. U.S., Inc.*, 2015 WL 5029282, at *5 (N.D. Cal. Aug. 25, 2015). All of Corcept's infringement claims meet these criteria.

First, with respect to the '348 and '495 patents, Corcept's lawsuit was automatically a sham because Corcept fraudulently listed those patents in the Orange Book, and then admitted that they did not "read on the Korlym label." (¶99.) *E.g.*, *In re Buspirone Pat. Litig.*, 185 F. Supp. 2d 363, 376 (S.D.N.Y. 2002) (suit to enforce improperly listed patents is a sham under *Noerr-Pennington*). The sham nature of these suits is confirmed by the fact that Corcept voluntarily dismissed its infringement claims in January 2021—and yet, "[b]etween the date Corcept sued Teva under the '348 and '495 patents, and the date Corcept voluntarily dismissed its infringement claims, Corcept had not learned any material new information bearing on the strength of its claims. Corcept's voluntary dismissal was an acknowledgement that its infringement claims were always objectively baseless and were brought in subjective bad faith for the purpose of delaying FDA approval of Teva's generic." (¶¶113-14.)

To be clear, it makes no difference that Teva filed an unsuccessful motion to dismiss the '348 and '495 infringement claims. As Defendants acknowledge, the Hatch-Waxman Act provides that filing a Paragraph IV certification is a technical act of patent infringement. (¶42; MTD Br. 1.) The court denied Teva's motion to dismiss for that reason alone, and "refused to review Teva's proposed label as part of its analysis." (¶112.) But the motion-to-dismiss decision "said nothing about whether Corcept's infringement claims were objectively baseless and pursued in subjective bad faith." (*Id.*) For this reason, courts allow sham litigation claims to go forward even when the underlying patent claim was not dismissed, because "[a] complaint can meet all the pleading requirements of the Federal Rules of Civil Procedure and still, as a factual matter, be frivolous." *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 232 (S.D.N.Y. 2019).

Corcept's additional patent infringement claims were likewise shams. The five other patents (in addition to the '348 and '495 patents) that Corcept asserted and then voluntarily dismissed—the '526, '242, '243, '216, and '801 patents (¶120)—are easily pled to be shams "because *none* of those

patents claim the proposed drug product or FDA-approved indication for Korlym, and *none* of the methods claimed in *any* of those patents can be found *anywhere* in the Korlym label or Teva's proposed mifepristone product label." (*Id.*) Defendants do not (and cannot) dispute that allegation. As such, there was no objective or subjective basis for Corcept to assert any of those patents against Teva. And again, all of Corcept's voluntary dismissals occurred without Corcept learning material new information, which confirms that these patent claims were brought in bad faith and never had an objectively reasonable chance of success. That is more than enough to overcome *Noerr-Pennington*. *See, e.g.*, *IPtronics*, 2015 WL 5029282, at *8 ("It is enough at this stage that IPtronics has alleged that Avago filed a complaint based upon documents later admitted to be insufficient to prove infringement and that it pressed those infringement claims using documents and new expert evidence that the ALJ also found insufficient to show what Avago claimed."); *Keurig*, 383 F. Supp. 3d at 231-32 ("DPPs go on to detail the deficient bases for the failed patent suits…. These assertions are sufficient to allege objective baselessness."); *Netflix, Inc. v. Blockbuster, Inc.*, 2006 WL 2458717, at *8 (N.D. Cal. Aug. 22, 2006) ("The objective component of Blockbuster's sham-litigation claim is that Netflix purportedly brought this action on the basis of clearly invalid and overbroad patents.").

Corcept's infringement claims under the '214 and '800 patents—the patents that went to trial—were likewise shams. Corcept's entire case rested on the allegation that Teva "induced infringement" of those patents. *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, 709 F. Supp. 3d 138, 142 (D.N.J. 2023). But at the time Corcept filed suit under the '214 patent, Corcept knew "there was no basis to suggest that Teva's proposed label would encourage infringement of the '214 patent." (¶116.) The same is true for the '800 patent, which is a continuation of the '214 patent. (MTD Br. 5.) These allegations are confirmed by the fact that when Corcept and Teva eventually went to trial, in September 2023, "Corcept failed to introduce credible record evidence that *anyone* ha[d] *ever* previously infringed the asserted claims…. This is notwithstanding the fact that Korlym has been commercially available since April 2012." *Corcept*, 709 F. Supp. 3d at 154, 156; *id.* at 154 (noting "the lack of record evidence demonstrating that anyone has ever practiced the claimed methods, including during the ten-year span since Korlym was approved"). Even Corcept's *own witnesses* "did not provide testimony that they had ever practiced Corcept's patented methods." *Id.* at 156. Corcept's complete

failure of proof raises a more-than-plausible inference that Corcept knew—at the time it sued—that it had zero basis to claim infringement, but did so anyway in order to delay Teva's launch.

It makes no difference that Judge Bumb declined to grant summary judgment against Corcept's '214 and '800 infringement claims. *E.g.*, *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 363 (D. Mass. 2004) ("[S]uccessful opposition to a summary judgment motion does not always conclusively establish the reasonableness of the claim in question."). Given the complete lack of evidence to support Corcept's '214 and '800 infringement claims, Teva has pled more than enough to defeat *Noerr-Pennington*. *E.g.*, *Competitive Techs. v. Fujitsu Ltd.*, 286 F. Supp. 2d 1118, 1152-53 (N.D. Cal. 2003) ("'sham exception' under *Noerr-Pennington*" was satisfied where complaint not only alleged "that the action was baseless, but also alleg[ed] specific facts in support of that allegation"); *IPtronics*, 2015 WL 5029282, at *8; *Keurig*, 383 F. Supp. 3d at 231-32; *Netflix*, 2006 WL 2458717, at *8.

In addition, *Noerr-Pennington* is inapplicable to each of these suits because, together, they represented "a series of lawsuits" brought "without regard to the merits and for the purpose of injuring a market rival." *Freeman v. Lasky, Haas & Cohler*, 410 F.3d 1180, 1184 (9th Cir. 2005).

B. Corcept's Infringement Suits Were Part Of A Larger Anticompetitive Scheme.

Even if Corcept's infringement lawsuits were not shams, they would still be actionable because "constitutionally protected lawsuit[s]" can give rise to antitrust liability if they are "part of a larger anticompetitive scheme." *Arista Networks, Inc. v. Cisco Sys. Inc.*, 2018 WL 11230167, at *9 (N.D. Cal. May 21, 2018). Specifically, "otherwise protected litigation can be a part of an 'anticompetitive scheme'" if "other aspects of the scheme independently produce anticompetitive harms. Once this step has been established, the court should ask whether the accused patent litigation was causally connected to these anticompetitive harms. If yes, an antitrust plaintiff may then include good faith patent litigation as part of the anticompetitive scheme." *Id.*

Teva's allegations easily satisfy both parts of that test. To satisfy step one, the FAC repeatedly alleges that Corcept's infringement lawsuits were part of a "multifaceted scheme to prolong Corcept's monopoly by stifling competition from Teva at every turn." (¶5; *see also, e.g.*, ¶¶1, 4, 6, 9, 10, 57, 203, 215, 217, 218, 222.) And there can be no question that "other aspects of the scheme"—namely, Defendants' exclusive dealing and bribery campaign—"independently produce anticompetitive

harms." *Arista*, 2018 WL 11230167, at *9; *id.* at *14. Step two is also clearly satisfied. The question at step two is whether Corcept's lawsuits were "arguably causally connected to the harms produced by" the anticompetitive conduct discussed at step one. *Id.* at *14. The answer is plainly yes: the FAC alleges that Corcept's patent lawsuits were a key component of Defendants' overall scheme to unlawfully maintain Corcept's monopoly. Corcept's lawsuits caused a delay in Teva's receipt of FDA approval and launch, which allowed Corcept and Optime to have years alone on the market, thus enabling them to entrench prescribers' reliance on Optime and fortify the anticompetitive effects of their exclusive dealing agreement. (¶¶152-54, 161.) Their time alone on the market also allowed them more opportunities to pay inducements to prescribers, shoring up their bulwark against future generic competition. (¶¶167-87.) In both ways, Corcept's infringement suits were "causally connected to the harms produced" by the other aspects of Defendants' scheme. *Arista*, 2018 WL 11230167, at *14. Even if those lawsuits were not shams, Teva can therefore pursue them as part of this case. *Id.*

C. Teva's Patent Litigation Claims Allege Antitrust Injury.

Defendants repeat the "antitrust injury" argument they made in response to Teva's Orange Book claim: that other causal factors (like Korlym's orphan drug exclusivity and Teva's decision not to launch at risk in August 2020) may have contributed to the delay in Teva's market entry. As discussed, this argument fails because it ignores Teva's well-pled allegations that Corcept forfeited its orphan drug exclusivity, and that Corcept's infringement suits caused significant delay regardless (¶¶77-80); it ignores the legal standard that a defendant's anticompetitive conduct need not be the only causal factor to satisfy causation, *Dolphin Tours*, 773 F.2d at 1509; *Solinger*, 586 F.2d at 1309; and it ignores that in the but-for world—a world in which Corcept followed the law—Teva would not have needed to launch at risk, because Corcept would not have brought its sham litigations in the first place.

D. Teva's Patent Litigation Claims Are Timely.

Defendants argue that Teva's patent litigation claims are untimely, insofar as they focus on lawsuits filed before June 2020. (This argument does not apply to Teva's claims related to Corcept's '800 and '801 patents.) But all of Teva's claims are timely, for reasons discussed at length above.

First, the clock did not start running until (at the earliest) Teva had FDA approval and entered the market, because until then, Teva did not have a cause of action and would not have been able to

allege antitrust injury and causation. *Aventis*, 2009 WL 10674453, at *2 ("*any* substantive antitrust claim" by competitor would fail where competitor "lacks FDA approval"); *Ethypharm*, 707 F.3d at 230, 237 (competitor's "sham litigation claims" fail for lack of antitrust standing "unless and until it acquires … FDA approval"). Separately, the clock did not start before Teva entered the market because any suit before then would have been too speculative. *Samsung*, 747 F.3d at 1204-05; *Oliver*, 751 F.3d at 1087. In addition, "an antitrust claim based on baseless litigation requires proof that the litigation was unsuccessful, which can only be determined upon the termination of the initial action." *Chemi SpA v. GlaxoSmithKline*, 356 F. Supp. 2d 495, 500 (E.D. Pa. 2005). Here, it was only in January 2021 that Corcept voluntarily dismissed its claims under the '348 and '495 patents, and December 2023 that Teva prevailed on the patents that went to trial. (¶¶113, 121.) Defendants cite *Pace Industries, Inc. v. Three Phoenix Co.*, 813 F.2d 234, 237 (9th Cir. 1987), as contrary authority, but that case did not involve a sham litigation claim at all; instead, it involved a suit to enforce an allegedly illegal contract. Finally, Defendants committed numerous overt acts that restarted the clock on Teva's patent litigation claims. Each suit between 2018 and 2023 was an "overt act" that restarted the clock on all of Teva's patent litigation claims. *See Samsung*, 747 F.3d at 1202-03. The same is true of Defendants' acts to "steer" patients to Optime, and their amendment and enforcement of their exclusive dealing agreement, all of which are "new and independent act[s]" that have "inflict[ed] new and accumulating injury" on top of the harms from Corcept's patent litigation misconduct. *Id.* at 1202-04. Teva's patent litigation claims are timely for any of these independent reasons.

IV. TEVA'S BRIBERY AND KICKBACK CLAIMS ARE PLAUSIBLE.

The FAC alleges in great detail that Corcept has been making illicit payments to prescribers for years, to induce them to continue routing prescriptions to Optime and selecting brand Korlym notwithstanding the availability of Teva's lower priced generic. These allegations are supported by an extensive analysis of publicly available payment and prescription data, and are reinforced by reports from investigative journalists detailing "substantial evidence of illegal payments paid by Corcept" to Korlym prescribers (¶179), allegations from whistleblowers in a securities class action that "Corcept's payments have been used to illicitly compensate physicians for prescribing brand Korlym" (¶169), and an active investigation by the U.S. Attorney's Office for the District of New Jersey to determine

"whether Corcept committed criminal or civil violations with respect to 'the sale and promotion of Korlym, *Corcept's relationships with and payments to health care professionals who can prescribe or recommend Korlym* and prior authorizations and reimbursement for Korlym.'" (¶185.)

Defendants' main response is to point out that Teva also makes payments to prescribers, in connection with legitimate speak programs and the like. This is not a serious argument. Payments to prescribers *can be* legitimate, but sometimes they are not—sometimes they are unlawful payments by a manufacturer to induce prescribes to favor the manufacturer's products over competitors. The FAC's detailed allegations demonstrate a plausible basis to suspect that Corcept's payments fall into the latter category. Defendants cannot secure dismissal of this claim by merely denying the well-pled facts on which the claim is based. *E.g.*, *United States, ex rel. Solis v. Millennium Pharms., Inc.*, 2015 WL 1469166, at *7 (E.D. Cal. Mar. 30, 2015) ("The SAC plainly makes averments [regarding bribery and kickbacks] that survive a pleadings challenge."); *Natural Immunogenics Corp. v. Newport Trial Grp.*, 2016 WL 11520711, at *11 (C.D. Cal. Aug. 1, 2016) (plaintiffs' allegations that defendants "paid or promised to pay" individuals "in exchange for their promise" were "sufficient to allege bribery").

Moreover, Defendants ignore the FAC's allegations that the payments made by Corcept "are astronomical and far outside the norm." (¶184.) As detailed in the FAC, public data shows Corcept paying prescribers many multiples—sometimes double-digit, or even triple-digit multiples—of what *all other manufacturers combined* paid to prescribers in the same specialty over the same time periods. (¶184.) And although Defendants say these allegations are without citation or support (MTD Br. 21), the CMS Open Payments website reports the "Specialty Mean" for each payment recipient, which allows one to compare the payments received by a specific prescriber to payments received by comparable prescribers. These highly suspicious, abnormal payments have drawn the scrutiny of federal prosecutors, journalists, and whistleblowers. They foreclose Defendants' attempt to deflect Teva's allegations by insisting that Corcept was behaving just like any other pharmaceutical company.

Defendants also assert that competition has not been harmed by the unlawful bribes and kickbacks described in the FAC. (MTD Br. 24-25.) This response is also a non-starter. Numerous courts have held that "[b]ribery can implicate the Sherman Act ... when it is directed toward suppressing competition in the market generally.... [I]f potential competitors are unable even to enter

the market and try to sell their products because of bribes, there is undoubtedly a harm to competition." *In re EpiPen Direct Purchaser Litig.*, 2021 WL 147166, at *24 (D. Minn. Jan. 15, 2021); *Mylan*, 666 F. Supp. 3d at 296-97 ("[W]hen bribery is offered to support a Sherman Act claim, the correct inquiry is ... whether [the defendant's] practices hobbled competition."); *Doron Precision Sys., Inc. v. FAAC, Inc.*, 423 F. Supp. 2d 173, 185 (S.D.N.Y. 2006) (same). The FAC clearly alleges that Defendants have engaged in a long-running, widespread scheme to hobble competition by paying bribes and kickbacks to prescribers. (¶¶167-87.) Defendants dispute the *extent* of the scheme—*e.g.*, *how many* prescribers were illicitly induced to favor Korlym over Teva's generic—but those are factual questions that require discovery. Given that there is undoubtedly a plausible basis to infer the existence of such a scheme and resulting harm to competition, Teva is entitled to uncover the extent of it through discovery.

V. TEVA'S STATE-LAW CLAIMS ARE PLAUSIBLE.

Defendants make numerous arguments about Teva's state-law claims, but these arguments all miss the mark. *First*, with respect to the UCL, "[b]ecause [Teva] ha[s] sufficiently stated a claim under the Sherman Act … , [Teva] ha[s] also stated a claim under the UCL's unfair and unlawful prongs." *B & R Supermarket, Inc. v. Visa, Inc.*, 2016 WL 5725010, at *12 (N.D. Cal. Sept. 30, 2016). *Second*, with respect to Section 16600, "Section 16600 … [has] been applied in cases considering agreements to secure monopolies or fix prices—the sort of context addressed by section 1 of the Sherman Act." *Meta Platforms, Inc. v. BrandTotal Ltd.*, 605 F.Supp.3d 1218, 1250 (N.D. Cal. 2022). *Third*, with respect to Teva's omnibus antitrust and consumer protection claims, these claims are adequately pled because Teva "ha[s] been clear about what wrongdoing has allegedly been committed by" Defendants. *Staley v. Gilead Sciences, Inc.*, 446 F.Supp.3d 578, 633 (N.D. Cal. 2020). *Finally*, with respect to Teva's unjust enrichment claim, the FAC "include[s] antitrust claims under the Sherman Act," which means Teva "ha[s] invoked a valid theory of recovery" and thus "claims for 'unjust enrichment' [can] proceed." *In re TFT-LCD (Flat Panel) Antitrust Litigation*, 2011 WL 4345435, at *1, *4 (N.D. Cal. Sept. 15, 2011).

CONCLUSION

The motion to dismiss should be denied. If the motion is granted in any respect, Teva should be given leave to amend. *Eminence Cap., LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

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Respectfully submitted,

By: */s/ Devora W. Allon*

Michael Shipley
KIRKLAND & ELLIS LLP
555 South Flower Street, 37th Floor
Los Angeles, California 90071
Tel: (213) 680-8400
michael.shipley@kirkland.com

Devora W. Allon, P.C.
Kevin M. Neylan, Jr.
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446 5967
devora.allon@kirkland.com
kevin.neylan@kirkland.com

Attorneys for Plaintiff Teva Pharmaceuticals USA, Inc.

FILER'S ATTESTATION

Pursuant to Civil L.R. 5-1(i)(3), regarding signatures, I, Devora Allon, attest that concurrence in the filing of this document has been obtained.

/s/ Devora W. Allon
Devora W. Allon

CERTIFICATE OF SERVICE

I hereby certify that on November 13, 2024, I caused to be filed the foregoing document with the United States District Court for the Northern District of California using the CM/ECF system and caused it to be served on all registered participants via notice of electronic filing.

/s/ Devora W. Allon
Devora W. Allon